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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/754,493  | 01/12/2004  | David C. Hacker      | 2401.0146.US        | 8280             |
| 36139   | 7590        | 09/28/2006           | EXAMINER            |                  |
| EPSTEIN & GERKEN<br>1901 RESEARCH BOULEVARD<br>SUITE 340<br>ROCKVILLE, MD 20850 |             |                      | LEE, YUN HAENG NMN  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3766                |                  |

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/754,493 | <b>Applicant(s)</b><br>HACKER ET AL. |  |
|                              | <b>Examiner</b><br>Yun H. Lee        | <b>Art Unit</b><br>3766              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 27 and 28 are objected to because of the following informalities: The limitation "said touch screen" lacks proper antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Digitimer, Ltd., D185 Brochure, 05/08/2001 (Brochure).

Regarding claim 1, the brochure discloses an intraoperative neural monitoring system comprising

a power source (page 6, Specifications, Other, Power); and

a stimulator (Digitimer D185 Multipulse Stimulator) powered by said power source to deliver a complete cycle of biphasic electrical stimulation for application to anatomical tissue.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2

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USPQ2d 1647 (1987). The stimulator is capable of delivering said complete cycle of biphasic electrical stimulation when used along with the D185-HB3 and D185-CB1 (page 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the system to be capable of automatically switching polarity, since it has been held that broadly providing an automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 2, the D185 system is capable of delivering a complete cycle of monophasic electrical stimulation by simply maintaining the polarity in one direction.

Regarding claim 3, the D185-CB1 can be used to select the polarity.

Regarding claim 4, see page 6, Specifications, Stimulus Output, Maximum current.

Regarding claim 5, the stimulus parameters can be selected to be identical, except for polarity, between the first group and the second group.

Regarding claims 6 and 10, see page 6, Specifications, Stimulus Pulse Rates, Train selections.

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Regarding claim 7, the number of pulses of both groups can be selected to be the same by using the front panel.

Regarding claim 8, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the pulse duration selectable in the range of 100 to 500 microseconds because Applicant has not disclosed that this range provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the D185 system.

Regarding claim 9, the interval between the first group of pulses and the second group of pulses is manually adjustable and depends on the operator. The intended use does not differentiate the claimed apparatus from the D185 system.

Regarding claim 11, a power console is shown on page 5 of the brochure.

Regarding claim 12, in addition to the above discussion, the brochure further discloses an activator (D185-CB1) actuatable by a user to complete an activation that starts delivery. The intended use statements do not differentiate the claimed apparatus from the D185 system. The delivery of said first group of pulses and said complete cycle of biphasic electrical stimulation can be done manually and the automation of such a process involves only routine skill in the art.

Regarding claim 13, the limitation “two-step procedure” is extremely broad and almost any step or steps can read on such a limitation. For example, in the case of actuating the D185-CB1 to complete activation, the two steps could be as follows: 1) thinking of actuating the D185-CB1 to complete activation; and 2) actuating the D185-CB1 to complete activation.

Regarding claim 14, the D185-CB1 is a hand switch.

Regarding claim 16, see the above discussions.

4. Claims 15 and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Digitimer, Ltd., D185 Brochure, 05/08/2001 (Brochure) in view of Viasys Healthcare, “Multi-Mode Program Plus (MMP Plus) User Guide”, Part Number 269-568803, June, 2000 (User Guide).

Regarding claim 17, it would have been obvious to one of ordinary skill in the art to use the D185 system in combination with the VikingSelect system to complement the continuous monitoring of sensory evoked potentials (SEP) during spinal and aortic surgery.

As discussed above, the D185 system clearly comprises:

a power console providing a power source; and

a stimulator electrically connectible to said power console, said stimulator being connectible to a pair of stimulating electrodes placed at areas of a patient's body and being capable of applying a second form of electrical stimulation to anatomical tissue of the patient, said stimulator capable of delivering said second form of electrical stimulation to a first one of the stimulating electrodes for return via a second one of the stimulating electrodes in a positive phase for said second form of electrical stimulation and delivering said second form of electrical stimulation to the second one of the stimulating electrodes for return via the first one of the stimulating electrode in a negative phase for said second form of electrical stimulation, said stimulator capable of delivering said second form of electrical stimulation up to a current amplitude of about 200 mA.

The User Guide discloses that the VikingSelect system comprises a patient interface unit electrically connectible to said power console, said patient interface unit being connectible to monitoring electrodes placed at areas of a patient's body (page 6), said patient interface unit being connectible to monopolar and bipolar stimulating probes.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The VikingSelect system is capable of detecting responses to a first form of electrical stimulation and said second form of electrical stimulation for display on a display screen (page 53). The VikingSelect system is also capable of applying said first form of electrical stimulation to anatomical tissue of the patient

(pages 23-28) through said monopolar and bipolar stimulating probes. The VikingSelect system is further capable of delivering said first form of electrical stimulation up to a current amplitude of about 30 mA (page 28).

Regarding claims 18-20 and 22-28, the limitations are either met by the above discussion or intended uses which are capable of being performed by the combined system of the D185 and the VikingSelect.

Regarding claims 15 and 21, Examiner takes Official Notice that it is well known to use touch screens for simplicity instead of using a mouse coupled to a screen. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include a touch screen in the VikingSelect system for simplicity.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

yhl